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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,217	11/25/1997	CHRISTOPHER C. BENZ	02307E-07111	4060

7590

05/21/2003

LAW OFFICES OF JONATHAN ALAN QUINE  
P.O. BOX 458  
ALAMEDA, CA 94501

EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

08/978,217

Applicant(s)

BENZ ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6-13,16-18,21-26,71,79 and 82-89 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 88 and 89 is/are allowed.

- 6) ☒ Claim(s) 1-4,6-13,16-18,21-26,71,79 and 82-87 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2002 has been entered.

2. Claim 79 was amended.

Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-89 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The objection to claim 79 is withdrawn in view of the amendment to claim 79.

#### ***Claim Rejections Maintained:***

5. The rejection of claims 1-4, 6-9, 16-19 and 21-26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

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Applicant's arguments have been carefully considered but are unpersuasive. Applicant argues that the "Revised Interim Written Description Training Examples" recognize that a claim may recite "stringent hybridization conditions". Applicant provided a copy of Example 9. However, upon review of Example 9, it was found that this example appears to teach an example where the "highly stringent conditions" are taught in the specification by the recitation of hybridization conditions. Example 9 contains the following sentence: "...wherein the complement of SEQ ID NO: 1 was used under highly stringent conditions (6XSSC and 65 degrees Celsius) for the isolation of nucleic acids....". Thus, the instant case is distinguished from example 9 in the Training Examples. Therefore, the examiner is not contradicting the PTO's own training materials and the Patent Office has not changed its position with respect to the suitability of "stringent hybridization".

The rejection of claims 1 and 16, because of the phrase "specifically hybridizes under stringent conditions" is maintained because the specification fails to define the limits of "stringent conditions". While the specification contains examples of what is considered stringent conditions, a teaching of an example is not adequate to define the metes and bounds of the polynucleotides encompassed by claims because the specification fails to teach what falls within "stringent conditions" and what does not.

6. Claims 1, 4, 6-13, 16, 21-26, 71, 79, and 82-85 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention is maintained for the reasons of record.

The rejections are maintained for the reasons of record. Applicant's arguments are unpersuasive because applicant fails to establish that the functional limitation "encoding a transcription factor" limits the breadth of the claimed genera to inventions for which the disclosure of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 15, and SEQ ID NO: 16 are representative embodiments. The family of transcription factors encompasses a broad range of structurally different compounds. Coupled with the fact that the hybridization language does not provide structural definition because the metes and bounds of "stringent hybridization conditions" are unclear, the claims encompass widely varying structures for which the disclosure of the embodied polynucleotides is not representative.

Applicant has argued that this rejection contradicts the PTO's training materials in the Interim Guidelines and cites Example 9 because Example 9 contains an example of a claim with hybridization language. However, the instant claims are distinguished from Example 9 because example 9 is drawn to a case where the hybridization conditions are "highly stringent" and are defined in the specification by hybridization conditions. Therefore, the genus of compounds in Example 9 are similar in structure; whereas in the instant case the genus of compounds vary widely in structure.

7. The rejection of claims 1, 2, 6-14, 21-26, 79, and 82-87 under 35 U.S.C. 102(e) as being anticipated by Kola et al, (U.S. Patent 5,789,200; issue Aug. 4, 1998; effective filing date Oct. 31, 1996) is maintained for the reasons of record.

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Applicant presents no specific arguments why this rejection should be withdrawn.

Applicant's comments with regard to providing a declaration under 37 C.F.R. 1.131 are noted.

However, applicant's attention is drawn to MPEP 2308.01 that instructs applicant to file a statement under 37 C.F.R. 1.608(a) or 37 C.F.R. 1.608(b) when a patent claims the same invention as what is claimed in an application to another. See also MPEP 2138.03: Interference practice operates to the exclusion of ex parte practice under 37 CFR 1.131 which permits an applicant to show an actual date of invention prior to the effective date of a patent or literature reference applied under 35 U.S.C. 102(a) or (e), as long as the patent is not a domestic patent claiming the same patentable invention. Ex parte Standish, 10 USPQ2d 1454, 1457 (Bd. Pat. App. & Inter. 1988) (An application claim to the "same patentable invention" claimed in a domestic patent requires interference rather than an affidavit under 37 CFR 1.131 to antedate the patent. The term "same patentable invention" encompasses a claim that is either anticipated by or obvious in view of the subject matter recited in the patent claim.). Subject matter which is available as prior art only under 35 U.S.C. 102(g) is by definition made before the applicant made his invention and is therefore not open to further inquiry under 37 CFR 1.131.

### ***Conclusion***

Claims 88 and 89 are allowable. Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-87 are rejected.

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Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
March 24, 2003

*Anne L. Holleran*  
*Patent Examiner*

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600